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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SUGHRUE MION, PLLC			EXAMINER	
2100 PENNSYLVANIA AVENUE, N.W.			GODFREY, KEITH JOSEPH	
SUITE 800				
WASHINGTON, DC 20037				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,321	VOGELEER ET AL.	
	Examiner	Art Unit	
	Keith J. Godfrey	1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 17-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/07/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-16) in the reply filed on 05/07/2007 is acknowledged. The traversal is on the ground(s) that the claimed subject matter of Groups I and II overlaps in comprehension of inventions. This is not found persuasive because a different field of search is still required, namely Group I classified in class 264/40.1 and Group II classified in class 425/148.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3, 5-6 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-3, 5, and 12 recite the limitation "powder quantity regulation". There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the quantity of powder". There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 7-10, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ebey (US 5322655).

As to claim 1, Ebey (US 5322655) teaches a method of controlling a multilayer tablet press mechanism with a rotary turret holding a plurality of dies for the formation of tablets from powders compressed between upper and lower (reciprocating) punches (abstract and col. 3, lines 59-62) including: consecutively supplying a quantity of material to be compressed into each die (col. 8, lines 44-45); carrying out a first layer compression (pre-compression) and a second layer compression (main-compression) (col. 4, lines 5-31); detecting (measuring) of the compression force by a first strain gauge transducer generating a control signal (first parameter) to establish a target weight of powder being compressed (col.1, lines 15-36 and col. 5, lines 3-13; 27-31; 43-51); detecting (measuring) of the compression force by a second strain gauge transducer generating a control signal (second parameter) to monitor layer compression force (tablet hardness) (col. 1, lines 15-36 and col. 5, lines 14-31 and col. 6, lines 17-24); using a feed-back loop incorporating measured error (deviation) from a setpoint for weight control (regulation) (col. 6, 64-68 and col. 7, lines 1-2; 18-26); and using a feed-

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back loop incorporating measured error (deviation) from a setpoint value to adjust (regulate) the final compression force (col. 7, lines 34-43).

As to claims 3-4, Ebey (US 5322655) teaches that regulation of compression force and tablet weight correspond to each other, and therefore, regulation of one is based on regulation of the other (col. 5, lines 26-31, 36-38; col. 7, lines 45-58).

As to claim 7, Ebey (US 5322655) teaches a method wherein the first value of compression information corresponds to a resultant force measured while compressing the first powder (pre-compression) to an established thickness (col. 10, lines 43-48).

As to claim 8, Ebey (US 5322655) teaches the first strain gauge transducer generates a control signal which is received by a corresponding first peak detector that determines the peak of the control signal (first parameter) that represents the maximum strain on punches at the associated precompression stage (col. 5, lines 43-50).

As to claim 9, Ebey (US 5322655) teaches the second value of compression information corresponds to a resultant force measured while compressing the second powder (main compression) to an established thickness (col. 10, lines 49-54).

As to claim 10, Ebey (US 5322655) teaches that a strain gauge transducer generates a control signal that is received by a corresponding peak detector that determines the peak of the control signal (second parameter) that represents the maximum strain on punches at the associated compression stage (main-compression) (col. 5, lines 50-58).

As to claim 14, Ebey (US 5322655) teaches a step of recalling the weight error and comparing the weight error to an acceptable error range (preset first rejection

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tolerance limits) to determine whether to accept or reject a tablet (col. 11, lines 21-37, and col. 12, lines 1-4).

As to claim 15, Ebey (US 5322655) teaches a step recalling the compression error (hardness) and comparing the compression error (hardness) to an acceptable error range (preset second rejection tolerance limits) to determine whether to accept or reject a tablet (col. 11, lines 21- 37 and col. 12, lines 5-9).

As to claim 16, Ebey (US 5322655) teaches a method of controlling a multilayer tablet press mechanism with a rotary turret holding a plurality of dies for the formation of tablets from powders compressed between upper and lower (reciprocating) punches (abstract and col. 3, lines 59-62) including: consecutively supplying a quantity of material to be compressed into each die (col. 8, lines 44-45); carrying out a first layer pre-compression and a first layer main compression (col. 5, lines 8-13) and a second layer pre-compression and a second layer main compression (col. 5, lines 16-25); detecting (measuring) of the compression force by a first strain gauge transducer generating a control signal (first parameter) to establish a target weight of powder being compressed (first layer) (col.1, lines 15-36 and col. 5, lines 3-15; 27-31; 43-51); detecting (measuring) of the compression force by a second strain gauge transducer generating a control signal (first parameter) to establish a target weight of powder being compressed (second layer) (col. 7, lines 39-43); using a feed-back loop incorporating measured error (deviation) from a setpoint for weight control (regulating the quantity of first material) (col. 6, 64-68 and col. 7, lines 1-2; 18-26); using a feed-back loop incorporating measured error (deviation) from a setpoint value to regulate the quantity

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of second material (col. 7, lines 39-42); and using a feed-back loop incorporating measured error (deviation) from a measured setpoint value to adjust (regulate) the final compression force (col. 7, lines 34-43; col. 8, lines 8-14).

As each and every element of the claimed invention is taught in the prior art as recited above, the claims are anticipated by Ebey (US 5322655).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebey (US 5322655), as applied to claims 1, 3-4, 7-10, and 14-16 above, in view of Hinzpeter (US 4062914).

The teachings of Ebey (US 5322655) are discussed above in the 102(b) rejection of claims 1, 3-4, 7-10, and 14-16 above but do not disclose regulation and rejection based on mean values of other measured values.

As to claim 5, Hinzpeter (US 4062914) teaches a method for monitoring the compression force of pelleting press rams including: a table compressing machine with strain gauge sensors connected to a mean value generator used to regulate compression force (hardness of tablet) (abstract and col. 2, lines 10-16; col. 3, lines 7-17; col. 4, lines 31-33). It would have been obvious to one of ordinary skill in the art at

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the time the invention was made to regulate the production of tablets using mean values of recorded process signals, as taught by Hinzpeter (US 4062914), in the method of Ebey (US 5322655) because recording and adjusting the compressing machine according to mean values allows for immediate recognition of process defects such as the breaking of a ram or double pressing of tablets (Hinzpeter (US 4062914), col. 2, lines 48-51). Because both of the references are concerned with a similar technical field, namely that of a producing tablets by compression, one would have a reasonable expectation of success from the combination.

As to claim 6, Hinzpeter (US 4062914) teaches that it is known to consistently carry out a process as long as the mean value of the monitored parameter falls within preset tolerance limits (col. 3, lines 19-26; it is interpreted that the process is only altered when the parameter falls outside of the tolerance limit). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out Ebey's control of tablet weight and compression using Hinzpeter (US 4062914) mean value tolerance limits for each of Ebey's tablet weight and compression control in order to avoid shutting down the machine every time a monitored signal falls slightly above or below a single setpoint (see Hinzpeter, col. 2, lines 24-29).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebey (US 5322655) as applied to claims 1, 3-4, 7-10, and 14-16 above, in view of Shimada et al. (US 3910737).

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The teachings of Ebey (US 5322655) are discussed above in the 102(b) rejection of claims 1, 3-4, 7-10, and 14-16 above but do not disclose compression degree preformed independently from the material quantity regulation.

As to claim 2, Shimada et al. (US 3910737) teaches a method of molding tablets including the weight of the moulded goods is regulated by the volume of the dies (col. 2, lines 51-54), and the compression degree is regulated by mechanical means (col. 2, lines 58-65; elements 25-29 adjust compression roll). It would have been obvious to one of ordinary skill in the art at the time the invention was made to independently control tablet compression and weight, as taught by Shimada et al. (US 3910737), in the method of Ebey (US 5322655) because isolating the regulation of tablet compression and quantity allows adjustment of both weight and thickness of molded goods instantly and promote production efficiency (see Shimada, col. 1, lines 47-49).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebey (US 5322655) as applied to claims 1, 3-4, 7-10, and 14-16 above, in view of Lewis (US 4817006).

As to claim 11, the teachings of Ebey (US 5322655) are discussed above in the 102(b) rejection of claims 1, 3-4, 7-10, and 14-16 above but do not disclose a parameter of time to control the compression steps.

Lewis (US 4817006) teaches a method of tablet press control mechanism including a compression peak signal based on a time interval (col. 9, lines 44-62). Therefore it would have been obvious to one of ordinary skill in the art at the time the

invention was made to include a time based peak compression, as taught by Lewis (US 4817006), in the method of Ebey (US 5322655) in order efficiently organize other parameter data associated with a particular time interval (Lewis (US 4817006), col. 9, lines 23-25). Because both of the references are concerned with a similar technical field, namely that of tablet presses, one would have a reasonable expectation of success from the combination.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebey (US 5322655) as applied to claims 1, 3-4, 7-10, and 14-16 above, in view of Furtwaengler et al. (US 3507388).

As to claims 12-13, the teachings of Ebey (US 5322655) are discussed above in the 102(b) rejection of claims 1, 3-4, 7-10, and 14-16 above but do not disclose a re-calibration of the parameters of production.

As to claims 12-13, Furtwaengler et al. (US 3507388) teaches a method for monitoring the weight of tablets formed in a tablet-making machine including continuous measurement of the pressure relationships in a tablet-press enabling the supervision of the tablets weight, hardness, and coherence (col. 1, lines 33-40). Furtwaengler et al. (US 3507388) also teaches how previous calibration of the system can enable the effective pressure to be readily determined from the recorded voltage values (col. 6, lines 27-29), and how re-calibration can bring rapid determination of desired tablet weight and compression relationships (col. 6, lines 48-64). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to

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carry out a re-calibration process, as taught by Furtwaengler et al. (US 3507388), in the method of Ebey (US 5322655) including tablet weight and compression (hardness) parameters during Ebey (US 5322655) molding process after a number of tablets are ejected from the die tables in order to insure the production of "good" (i.e. desired) product characteristics (Furtwaengler et al. (US 3507388), col. 6, lines 59-64). Because both of the references are concerned with a similar technical field, namely that of manufacturing tablets, one would have a reasonable expectation of success from the combination.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith J. Godfrey whose telephone number is 571-272-6391. The examiner can normally be reached on 8:00-5:00 Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina A. Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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kjg

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INSO
SUP. CHRISTINA JOHNSON
SUPERVISORY PATENT EXAMINER
7/20/07